K041592
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510(k) Summary

Submitter:	Theken Surgical 283 E. Waterloo Rd. Akron, Ohio 44319
Contact Person:	Randy Theken Manager, Theken Surgical
Trade Name:	Coral™ Spinal System
Common Name:	Screw/Rod spinal instrumentation
Classification:	**KWP** 888.3050 – Spinal Interlaminal Fixation Orthosis **MNI** 888.3070 – Pedicle Screw Spinal System **MNH** 888.3070 – Spondylolisthesis Spinal Fixation System **KWQ** 888.3060 – Spinal Intervertebral Body Fixation Orthosis **NKB** 888.3060 – Spondylolisthesis Spinal Fixation System
Predicate Device:	Sofamor Danek Colorado II Spinal System, K991031 (et al) DePuy-Motech Moss Miami Spinal System, K955348 (et al)
Device Description:	The Coral™ Spinal System consists of a variety of shapes and sizes of screws, rods, hooks, cross-connectors, and connecting components. Coral™ Spinal System components can be rigidly locked creating a rigid construct for promoting fusion. Coral™ Spinal System implant components are fabricated from medical grade titanium alloy described by such standards as ASTM F67, ASTM F136, ISO 5832-3, and ISO 5832-2. Alternatively, the entire system may be made out of medical grade stainless steel described by such standards as ASTM F138, ISO 5832-1, and ISO 5832-9. ***Caution use of dissimilar metals, i.e. stainless steel and titanium must not be used in combination, but must be used independently.***
Intended Use:	The Coral(tm) Spinal System is a non-cervical spinal fixation device intended for use as a posterior pedicle screw fixation system, a posterior non-pedicle screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.
Substantial Equivalence:	The Theken Surgical Coral™ Spinal System is substantially equivalent to other legally marketed devises. Mechanical testing data under ASTM F-1717 was provided or referenced to demonstrate substantial equivalence.

SEP 16 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Mr. Randy R. Theken
President
Theken Surgical
283 East Waterloo Road
Akron, Ohio 44319

Re: K041592
Trade/Device Name: Coral™ Spinal System
Regulation Number: 21 CFR 888.3050, 888.3060, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis; spinal intervertebral body fixation orthosis; pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, KWQ, KWP, MNH, MNI
Dated: June 7, 2004
Received: June 14, 2004

Dear Mr. Theken:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4649. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041592

Device Name: Coral™ Spinal System

Indications For Use:

The Coral™ Spinal System is a non-cervical spinal fixation device intended for use as a posterior pedicle screw fixation system, a posterior non-pedicle screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041592